

REMARKS

After entry of this response, Claims 17-27 remain pending in the present application. Claims 17, 21, and 22 are amended. No new matter has been added by these amendments. Applicant respectfully requests reconsideration by the Examiner in light of the following remarks.

I. Rejections under 35 USC §112

Claim 22 stands rejected under 35 USC 112, first paragraph, as allegedly failing to comply with the written description requirement with regard to the subject matter of triple chamber cardiac resynchronization therapy. Applicant respectfully traverses.

Contrary to the Examiner's assertion, the subject matter of triple chamber resynchronization is clearly supported in the application as filed. This support can be found, for example, at page 11, lines 20 to 23 and at page 12, lines 1-4.

As the Examiner is well aware, nothing in the first paragraph of 35 USC 112 requires an Applicant to use claim language that is identical to that contained in the specification. Indeed, as the Examiner notes, "three chambers, two ventricles and an atria, triple chambers, are accepted to be included in this therapy [the *therapy* being cardiac resynchronization therapy]." (emphasis added). See Office Action, page 4, last paragraph. The sections cited in support of the triple chamber subject matter above similarly state that the triple chamber cardiac resynchronization therapy is atrial synchronized bi-ventricular pacing, i.e., an atria and two ventricles, or three chambers.

Accordingly, Applicant respectfully requests withdrawal of the rejection of Claim 22 under the first paragraph.

II. Rejections under 35 USC §103

Claims 17, 18, and 20-27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the '428 patent to Obel et al. (Obel) and the '326 patent to Collins (Collins) in view of the '898 patent to Limousin (Limousin). Claim 19 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Obel, Collins and Limousin as applied to Claim 17 and further in view of the '187 patent to Adams. Applicant respectfully traverses.

In the present application, an apparatus is provided that combines the therapy treatments of cardiac resynchronization and nervous tissue stimulation to improve cardiac performance and efficiency. Among other things, the nervous tissue stimulation of the present application, when titrated to the appropriate levels, will substantially mimic beta-blockers by achieving the desired afterload (blood pressure) as well as preload (volume retention). Thus in amended Claim 17, for example, the nervous tissue stimulation is titrated based upon monitored physiologic parameters to optimize the pressure-volume relationship. Support for the amendments to Claim 17 can be found, for example, at page 11, lines 17-18; page 12, lines 1-2 and lines 18-19; and page 13, lines 1-2.

None of the cited references, alone or in combination, teach or suggest titrating the electrical stimulation based on the physiological parameters to achieve an optimal pressure-volume relationship of the patient's heart as stated, for example in Claim 17. In Obel, the device provides electrical stimulation controlled by pre-programmed pulse trains, which may also be synchronized to the patient's heart activity, e.g., start at the beginning of the heart cycle. See col. 4, lines 9-20; col. 8, lines 40-43. Nothing in Obel's disclosure teaches, suggests, or implies that this electrical stimulation can be titrated to optimize the pressure-volume relationship. Similarly, the Collins and Limousin references are devoid of the teaching of titrating the electrical stimulation. In Collins, the microprocessor generates the characteristics of the neural stimulation pulses according to the timing of codes written to the neural stimulation control bus 22 (pre-determined). See col. 10, lines 22-25. Like Obel, these pulses may be synchronized with respect to intrinsic or paced cardiac activity or asynchronous, i.e., according to the operations of an internal timer. See col. 11, lines 36-44. However, like Obel, the Collins reference is silent on titration of the stimulation. With regards to Limousin, it is undisputable that the reference is devoid of a disclosure of neural stimulation and thus cannot remedy the deficiency in the Obel and Collins references.

As stated in Claim 17, the nervous tissue stimulation is titrated based on monitored physiologic parameters to optimize the pressure-volume relationship. In other words, a feedback mechanism approach based on physiologic parameters is used in the application of the stimulation to achieve an optimal pressure-volume relationship

of the heart. Thus combined therapy of nervous tissue stimulation in conjunction with cardiac resynchronization therapy provides improved cardiac efficiency that reduces the neuro-endocrinological burden of the patient.

Accordingly, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. § 103(a) of the pending claims as unpatentable over Obel in view of Collins and further in view of Limousin.

III. Conclusion

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

Should any issues remain outstanding, the Examiner is urged to telephone the undersigned to expedite prosecution.

Respectfully submitted,

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